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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,636	10/20/2003	Patrick Rambaud	0501-1017-1	1794

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YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
WHALEY, PABLO S	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,636	RAMBAUD, PATRICK	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-24 drawn to a method and system of managing batches of immunocompetent cells collected from human or animal subjects for deferred use, classified in class 702, subclass 019. If this Group is elected, then the below summarized four specie elections are also required.

Group II: Claims 25-26 drawn to a method and system for determining parameters of a protocol for a deferred use of immunocompetent cells from a human or animal subject's personal library, classified in class 702, subclass 019. If this Group is elected, then the below summarized two specie elections are also required.

The inventions are distinct, each from the other because of the following reasons:

While the inventions of **Group I and Group II** are related, they consist of distinct steps and therefore have different modes of operation, different functions, or different effects. In the instant case the inventions of **Groups I and II** have different functions. Group I is directed to a method and system for managing batches of immunocompetent cells collected from human or animal subjects for deferred use, whereas Group II is drawn to a method and system for determining parameters of a protocol for a deferred use of immunocompetent cells from a human or animal subject's personal library. Critical limitations disclosed in Group I that are

distinct from Group II include: implementing methods in a therapeutic protocol including re-injecting lymphocytes on a human or animal subject, implementing methods in a therapeutic protocol for transfusing blood from a donor to a receiver, and successive status characterizing information comprising bioelectronic information and information obtained by processing sensible crystallization images. Group II discloses no such limitations. While Group I discloses the step drawn to determining parameters of a deferred-use protocol, it does not disclose the critical limitations of Group II drawn to measuring physical/biological characteristics, or processing characteristic information in an information system. Thus, the search for the two groups together would present an undue search burden as they are directed to systems and methods that are generally distinct and separate.

SPECIE ELECTION REQUIREMENT FOR GROUP I

This application contains claims directed to patentably distinct species of the claimed invention. If Group I is elected, the applicant is further required to make the following specie elections for purposes of examination. The applicant must elect between Specie I-A **or** Specie I-B. The applicant must further elect a biological sample type (Specie II), status-characterizing information (Specie III), and a therapeutic protocol (Specie IV) as follows:

Specie I-A: Method as set forth in Group I, wherein immunocompetent cells are collected from a human.

Specie I-B: Method as set forth in Group I, wherein immunocompetent cells are collected from an animal.

Specie II: Method as set forth in Groups I, wherein status-characterizing information is obtained by processing measurements made from one of the following sample categories: (i) blood, (ii)

hair, (iii) secretions, (iv) non-secretion fluid, or (v) a specific combination (i.e. two) from the set of (i)-(iv).

Specie III-A: Method as set forth in Group I, wherein the status-characterizing information comprise bioelectronic information.

Specie III-B: Method as set forth in Group I, wherein the status-characterizing information comprise information obtained by processing sensible crystallization images.

Specie IV-A: Method as set forth in Group I, implemented in a therapeutic protocol including re-injecting lymphocytes T with a specific cytotoxicity activity after ex-vivo expansion.

Specie IV-B: Method as set forth in Group I, implemented in a therapeutic protocol including re-injecting lymphocytes by the lymphatic way.

Specie IV-C: Method as set forth in Group I, implemented in a therapeutic protocol including a step for checking the harmlessness of the lymphocytes before re-injection.

Specie IV-D: Method as set forth in Group I, implemented in a therapeutic protocol including an ex-vivo processing between lymphocytes and a vaccine before re-injection.

Specie IV-E: Method as set forth in Group I, implemented in a therapeutic protocol including an ex-vivo processing and allergic desensitization of the lymphocytes before re-injection.

Specie IV-F: Method as set forth in Group I, implemented in a therapeutic protocol for transfusing blood from a donor to a receiver.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claims 1, 4, 5, 6, 9, 10, and 15-19, 23, and 24** are generic to the above species for Group I. Specie I is distinct as the health/psychological status of animals and humans is drawn to divergent subject matter. Specie II is distinct as the biological material disclosed has different chemical elements and is therefore drawn to divergent subject matter. Furthermore, searching the invention of Group I drawn to measurements obtained form biological "secretions" along with hair, blood, and non-secretion fluid is an undue search burden. Specie III is distinct because the bodies of literature that describe bio-electronic information and information obtained by processing sensible crystallization images is not coextensive. Specie IV

is distinct it is drawn to distinct therapeutic protocols. Thus, the search for all species together would present an undue search burden as they are directed to separate divergent subject matter.

SPECIE ELECTION REQUIREMENT FOR GROUP II

This application contains claims directed to patentably distinct species of the claimed invention. If Group II is elected, the applicant is further required to make the following specie elections for purposes of examination. The applicant must elect between Specie V-A **or** Specie V-B. The applicant must further elect a sample type (Specie VI) as follows:

Specie V-A: Method as set forth in Group II, wherein immunocompetent cells are collected from a human.

Specie V-B: Method as set forth in Group II, wherein immunocompetent cells are collected from an animal.

Specie VI: Method as set forth in Group II, wherein status-characterizing information is obtained by processing measurements made from one of the following sample categories: (i) blood, (ii) hair, (iii) secretions, (iv) non-secretion fluid, or (v) a specific combination from the set of (i)-(iv).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claims 25 and 26** are generic to the above species for Group II. The species are distinct for reasons previously mentioned. Thus, the search for all species together would present an undue search burden as they are directed to separate divergent subject matter.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ardin H. Marschel 11/8/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER